## Optimizing Prosthetic Gait

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# Feasibility and validity of a graded one-legged cycle exercise test to determine peak aerobic capacity in older people with a lower limb amputation

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**Abstract**

Information concerning the exercise tolerance and aerobic capacity is imperative for generating effective and safe exercise programs. However, for older people with a lower limb amputation, a standard exercise test is not available. The primary aim of the present study was to determine whether a graded one-legged peak exercise test is feasible and provides a valid assessment of peak aerobic capacity in older people walking with a lower limb prosthesis. A total of 36 older people with a lower limb prosthesis and 21 people who were able-bodied (controls; overall mean age = 61.7 years, SD = 6.1) performed a discontinuous, graded, one-legged, exercise test. The peak respiratory exchange ratio ($RER_{peak}$) was used as an indicator of maximal effort. The controls performed an additional two-legged exercise test in provide insight into differences the testing modes. All participants were able to perform the exercise test. Electrocardiographic tracings and blood pressure were adequately monitored. The controls and the people with a lower limb amputation were able to stress the cardiovascular system to a similar extent. Analyses of construct validity revealed that the peak aerobic capacity measured with the one-legged exercise test was able to distinguish between participants on the basis of age, body mass index and sex to a similar extent as the conventional two-legged exercise test. The graded one-legged exercise test was feasible, and provided a valid assessment of peak aerobic capacity and exercise tolerance in older people walking with a lower limb prosthesis.

## Introduction

Graded exercise testing has been widely acknowledged and implemented as a valid and effective way to assess physical fitness, diagnose coronary artery disease, allow for risk stratification [83, 154], and determine the presence of other factors that limit exercise [115, 138]. Additionally, graded exercise testing allows for the development of safe, effective and individualized exercise programs and enables the objective evaluation of the exercise capacity in several groups of patients [115, 138, 154]. People with an amputation at the level of the lower limb are more likely to have a reduced aerobic capacity and are at an increased risk of coronary artery disease as a result of preexisting comorbidities [3, 122] or hemodynamic changes [156]. Exercise testing can provide clinicians with important information concerning the exercise capacity and the cardiac condition of these patients [66, 180]. In addition, previous research showed that graded exercise testing can be used to predict walking ability [24-25, 66] in people with an amputation at the level of the lower limb.

For testing people with a lower limb amputation, special consideration concerning the exercise mode and protocol used is necessary. For example, the impaired motor system, reduced muscle mass, balance problems, and problems associated with prolonged stump loading make application of the commonly used and recommended treadmill exercise test [83] unsuitable [66, 210].

Several alternative exercise modes have been used [3, 12, 21-25, 29, 37, 66, 70, 122, 133, 170] and compared [118, 220] in people with a lower limb amputation. The two most commonly used exercise modalities are arm ergometry and one-legged exercise. However, several arguments favor one-legged exercise test for people with a unilateral lower limb amputation. First, one-legged exercise targets the remaining, still relatively large muscle group of the intact limb, resulting in a higher measured peak aerobic capacity than exercise with the small muscle mass of the upper extremities (e.g. arm exercise). Second, one-legged exercise results in lower perceived exertion and lactate values than arm ergometry, making one-leg cycling an exercise modality that is better tolerated [160]. Third, one-legged exercise allows for a functional evaluation of exercise capacity because it targets the muscles that are active during walking – a strenuous activity for people with a prosthesis [226]. Finally, one-legged exercise allows for reliable electrocardiogram (ECG) tracing because of limited movements of the upper extremities [76, 197].

Tolerability and safety can be further improved by applying a discontinuous protocol; rest intervals in between exercise steps allow for noise-free ECG and adequate blood pressure recordings. Furthermore, the reduced intramuscular pressure during the rest intervals allows for metabolites to be transported over the cell membrane, possibly leading to a reduced feeling of local fatigue.

A pilot study showed that a discontinuous protocol consisting of 90 seconds of exercise separated by 30 seconds of rest, did not alter obtained the peak oxygen consumption during one-legged exercise, and it was experienced by participants as more comfortable than continuous exercise [231].

In several studies, a one-legged exercise test has been used to either predict [118], or directly measure [21-25] the peak aerobic capacity in people with a lower limb amputation. However, the feasibility of a discontinuous protocol in older people has not been studied. More importantly, because none of the previously reported studies included an age-matched control group, information about possible differences in exercise response between the older people who are able-bodied (controls) and people with a lower limb amputation is lacking.

The primary aims of the present study were to describe a discontinuous, graded, one-legged, peak exercise test and to determine whether it is feasible and provides a valid assessment of the peak aerobic capacity in older people currently walking with a unilateral lower limb prosthesis. With respect to feasibility, we hypothesized that study participants with an amputation were able to perform this exercise without being limited by feelings of discomfort other than fatigue and that the exercise set-up would provide adequate monitoring of the participants to create a safe test environment. Concerning validity, we hypothesized that both participants that were able-bodied and the people with a lower limb amputation would reach the criteria for maximal aerobic exercise. A secondary aim was to determine the concurrent validity of the one-legged exercise test in the older subjects. This was done by comparing the peak aerobic capacity obtained by the same group of controls during the one-legged and the conventional two-legged exercise test. The construct validity of the one-legged exercise test was determined by analyzing whether the peak aerobic capacity measured with the one-legged exercise test was able to distinguish between study participants on the basis of age, body mass index (BMI) and sex to the same extent as when measured using the conventional two-legged exercise test.

## Methods

### *Subjects*

A total of 37 people with a lower limb prosthesis and 21 people who were able-bodied (controls) agreed to participate in this study (mean age 61.7, SD 6.1). One individual with a lower limb amputation had abnormalities on the resting ECG and complained of chest pain before the exercise test; therefore, this individual was excluded from the study. Of the remaining 36 people with an amputation,

**Table 1. Participants' characteristics**

| | people with an amputation n = 36 | able-bodied controls n = 21 |
|---|---|---|
| Age (years) | 62.2 (6.2) | 60.8 (5.9) |
| Sex (men/women) | 26/10 | 14/7 |
| Weight (kg) | 82.4 (15.5) | 81.1 (14.3) |
| BMI | 26.7 (5.2) | 25.7 (3.7) |
| Years since amputation | 27.2 (23.0) | not applicable |

Abbreviations: BMI, Body Mass Index

26 had undergone amputation because of trauma and 10 had undergone amputation because of vascular deficiency. Of the 37 people with an amputation, 14 had amputations at the trans-femoral level and 23 at the trans-tibial level. The participants were aged between 50 and 75 years of age (Table 1). All participants with an amputation were able to walk four minutes with their prosthesis. All participants had had their amputation for more than 1 year before participation (Table 1), but a great deal of variation existed among participants (average years since amputation 27.2, range 1-66; Table 1).

Exclusion criteria were an absolute contraindication for exercise [143, 146], an impairment of cognitive function that would hamper understanding of the instructions, and a history of neurological diseases. None of the participants was extremely active or engaged in competitive sports. Before participation in the study, all participants with an amputation underwent an examination by a physician and medication intake was noted. After both verbal and written clarifications of the test protocol, the participants gave written informed consent.

*Exercise test*

Participants were asked to refrain from drinking coffee and eating large meals at the day of the test and to avoid excessive exercise in the 24 hours preceding the exercise test. Before the test, the resting ECG and blood pressure were recorded. The ECG electrodes (CardioPerfect, Welch Allyn Benelux, Delft, The Netherlands) were placed as described by Edenbrandt and colleagues (1989) [61]. The ECG was continuously monitored throughout the test, and blood pressure was recorded during each rest phase and after completion of the test.

The exercise test was performed with an electronically braked cycle ergometer (Lode Corival, Lode B.V., Groningen, The Netherlands) while using a discontinuous protocol in which 90 seconds of exercise was followed by a 30-second rest phase. Participants with a lower limb amputation pedalled with their non-amputated limb, whereas for the participants who were able-bodied the pedalling limb was randomly assigned. The nonexercising leg was positioned on a cushioned

**Figure 1. Experimental set-up**

The exercise test was performed using an electronically braked cycle ergometer. The exercising non-amputated leg was placed on a pedal with a large footplate and attached with Velcro straps (the pedal is shown in the inset). The non-exercising leg was placed at a cushioned plateau. When necessary, the cycling rhythm could be improved by guiding the leg through the pull phase of the cycling motion.

extension plateau with the hip in approximately 90 degrees of flexion. Participants with a lower limb amputation were free to choose whether they wore their prosthesis during the test (Figure 1). The exercising leg was placed on a pedal with a large footplate and secured with Velcro (Velcro USA Inc, Manchester, New Hampshire) straps (Figure 1, inset). Participants were encouraged to maintain the frequency of pedalling at 50 to 60 revolutions per minute. Contrary to two-legged cycling, one-legged cycling requires torque to be exerted during both the push and pull phases of pedaling. For some participants this characteristic led to a distorted cycling rhythm, especially at the end of the pull phase. Cycling rhythm improved when participants were manually guided through the pull phase. Sufficient time was given for participants to become familiar with the setup.

For ensuring a time to exhaustion of 8 to 12 minutes [83, 146, 155], the starting workload and incremental steps were individually determined on the basis of the rate of perceived exertion (RPE) while participants pedaled at a range of workloads. More specifically, when participants indicated that the workload was somewhat hard, this workload was set as the initial starting workload. Incremental steps were based both on participants' daily activity level and the subjective prediction of exercise performance by the test leader. This resulted in incremental steps for participants who were somewhat active, between 15 and 20 W, and for participants with lower physical activity levels, between 5 and 10 W. During the rest phase, the workload was reduced to 10 W; during the subsequent

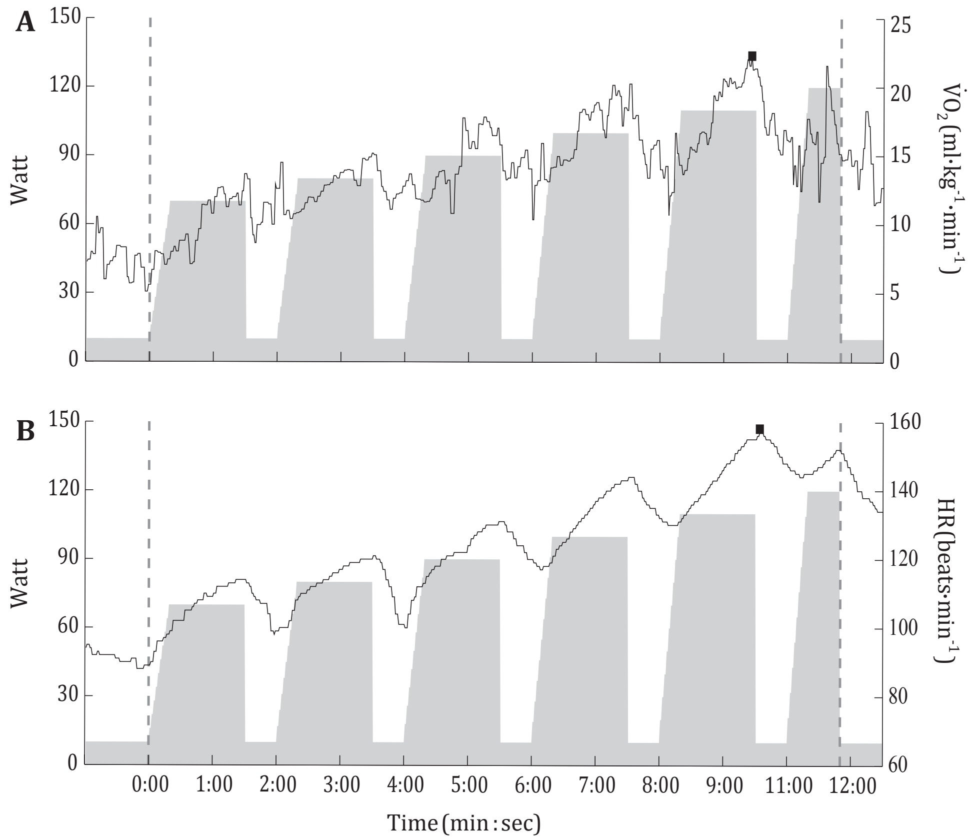


**Figure 2. The oxygen uptake and heart rate response.**

**(A)** Oxygen uptake response (oxygen consumption [$\dot{V}O_2$]) and **(B)** heart rate (HR) of a typical participant with a lower limb amputation during the one-legged exercise protocol. The load during the exercise protocol is depicted as a gray area; each exercise bout of 90 seconds is followed by 30 seconds of rest. The start and end of the exercise test are marked with vertical dashed lines. Both peak oxygen consumption and peak heart rate are depicted by a black square. This participant was unable to finish the last exercise phase; therefore, the participant's peak power output was 110 W.

exercise phase, workload was gradually increased over a period of 20 seconds toward the target workload (Figure 2). Throughout the exercise test, participants were verbally encouraged. The test was ended when either pedaling frequency dropped below 50 revolutions per minute, a further increase in workload did not lead to an increase in oxygen uptake, irregularities in the ECG, or extreme blood pressure changes were noted, or when participants indicated that they wanted to stop. Directly after the test was stopped, blood pressure was recorded and participants were asked which factor limited further exercise.

The control group performed an additional, two-legged exercise test with the same discontinuous protocol as used during the one-legged exercise test. However, because power output is higher when exercise is performed with two legs than when it is performed with one leg, the starting workload and incremental steps were higher during the two-legged exercise test. The tests were separated by a minimum of two days.

*Outcome parameters*

Oxygen consumption was measured breath-by-breath using open-circuit respirometry (Oxycon Delta, CareFusion, Houten, The Netherlands) Breath-by-breath variability was attenuated with a three-breath smoothing average filter. The peak aerobic capacity ($\dot{V}O_{2peak}$, $ml \cdot kg^{-1} \cdot min^{-1}$), peak respiratory exchange ratio ($RER_{peak}$) and peak heart rate ($HR_{peak}$, beats $\cdot\, min^{-1}$) were determined as the highest value attained during the last or penultimate exercise phase. In addition, $HR_{peak}$ was presented as the percentage of the predicted $HR_{peak}$ ($HR_{\%predicted}$). The predicted $HR_{peak}$ was calculated using the equation proposed by Tanaka and colleagues (2001) [201] Only data from participants not using beta-blockers were used to calculate $HR_{peak}$ and $HR_{\%predicted}$. The peak power output ($P_{peak}$) was presented as the highest workload completed by a participant. The criterion for maximal exercise effort was defined as a $RER_{peak}$ value of greater than 1.1 [113, 155]. The performance-limiting factors, indicated by the participants at the end of the exercise test, were placed in three groups according to whether the indicated limited factor represented fatigue of the legs (e.g. local fatigue), general fatigue or other remaining factors (such as pain in the chest region or saddle discomfort).

*Data analysis*

Descriptive statistics were generated for characteristics of the participants, protocol, and physiological parameters. Differences between the controls and the participants who had an amputation with respect to participants' characteristics, protocol and physiological outcome parameters were analyzed using an unpaired *t* test (SPSS Version 16.0, SPSS inc., Chicago, IL,USA) To determine whether participants with an amputation and controls differed with respect to the indicated performance-limiting factors, a chi-square test was performed.

Differences in protocol and physiological parameters between the one-, and two-legged exercise test, both performed by the controls, were analyzed with a paired-sample *t* test. To determine whether values reached on the one-legged exercise test were consistent with values reached in the two-legged exercise test, concurrent validity was assessed by calculating the two-way mixed single-measure intraclass correlation coefficient ($ICC_{(3,1)}$, type consistency) [196]. The

**Table 2. Limiting factors**

| | One-legged | | Two-legged |
|---|---|---|---|
| | amputees n = 36 | able-bodied controls n = 21 | able-bodied controls n = 21 |
| Fatigue of the leg* | 83.3% (n = 30) | 61.9% (n = 13) | 42.9% (n = 9) |
| General fatigue | 16.7% (n = 6) | 38.1% (n = 8) | 57.1% (n = 12) |
| Other | 0% (n = 0) | 0% (n = 0) | 0% (n = 0) |

* Significantly more participants indicated fatigue of the legs as a limiting factor during the one-legged exercise ($p < .001$).

criterion for agreement was set at .75 for the lower limit of the 95% confidence interval (CI) of the $ICC_{(3,1)}$ [135]. The standard error of the estimate was calculated to determine the magnitude of the difference between the exercise tests. To test whether the performance-limiting factor indicated by the able-bodied controls was different between exercise modalities, a McNemar test for paired responses was performed. Construct validity was tested by use of multiple linear regression analyses with as the dependent variable and age, BMI and sex as the independent variables. The associations found for the one-legged exercise test were compared with those found for the two-legged exercise test. Because only the controls performed the subsidiary two-legged exercise test, only data obtained from the controls were entered in the model. The dependent variable, $\dot{V}O_{2peak}$, $ml \cdot kg^{-1} \cdot min^{-1}$ was natural log transformed to improve model fit. The level of significance was set at $p < .05$.

## Results

### *Feasibility*

All participants were able to complete the exercise test and no abnormalities on the ECG tracing were noted during or after the exercise test. All participants indicated that fatigue (and not any other factor) was the reason for stopping the test. Overall (n = 57) significantly more participants indicated fatigue of the leg (as opposed to general fatigue) to be the performance-limiting factor during one-legged exercise ($\chi^2 = 14.754$, $p < .001$; Table 2). There was no statistical difference between groups in the indicated limiting factors ($\chi^2 = 3.287$, $p = .07$). Although the initial starting workload and incremental steps were, on average, lower in participants with a lower limb amputation, the differences were not significant. Likewise, total exercise times did not differ between the groups. On average, total exercise times remained below the recommended 12 minutes (Table 3) [83, 155].

**Table 3. Mean protocol meters (±SD).**

| | One-legged | | Two-legged |
|---|---|---|---|
| | amputees n = 36 | able-bodied controls n = 21 | able-bodied controls n = 21 |
| Start workload (W) | 67.8 (29.0) | 74.5 (15.4) | 115.5 (28.5)* |
| Increments (W) | 15.1 (4.1) | 17.2 (3.1) | 22.5 (4.8)* |
| Time to exhaustion (min:sec) | 8:23 (2:57) | 9:07 (3:00) | 10.16 (3:49) |
| Peak power output (W) | 121.0 (40.8) | 141.9 (36.3) | 216.0 (63.0)* |

* Significantly different from the value found using the one-legged exercise test (both tests are performed by controls; $p < .05$).
Abbreviation: $P_{peak}$, peak power output.

*Validity*

Overall (n = 57), the predefined criterion for maximal effort was reached (mean $RER_{peak}$ was 1.3, SD = 0.1; Table 4) during the one-legged exercise test. However, four participants with an amputation failed to reach a $RER_{peak}$ of greater than 1.1 (range = 1.02 - 1.08). Overall (n = 57), participants reached, on average 89.1% (SD = 11.4%) of their age-corrected predicted $HR_{peak}$ value. Neither $HR_{peak}$ and $RER_{peak}$ values differed between the controls and the participants with a lower limb amputation ($p = .40$, $p = .93$, respectively), indicating that both groups

**Table 4. Mean peak physiological values (±SD).**

| | One-legged | | Two-legged |
|---|---|---|---|
| | amputees n = 36‡ | able-bodied controls n = 21 | able-bodied controls n = 21 |
| $\dot{V}O_{2peak}$ (ml·kg$^{-1}$·min$^{-1}$) | 25.1 (7.9)* | 30.8 (10.3) | 37.9 (11.0) † |
| $\dot{V}CO_{2peak}$ (ml·kg$^{-1}$·min$^{-1}$) | 26.4 (8.8)* | 33.3 (11.4) | 40.0 (12.0)† |
| $RER_{peak}$ | 1.3 (0.2) | 1.3 (0.1) | 1.3 (0.1) |
| RR (beats·min$^{-1}$) | 44.5 (10.9) | 48.0(13.1) | 42.9 (9.3)† |
| $\dot{V}E$ (l·min$^{-1}$) | 77.1(22.7)* | 91.1 (27.3) | 105.6(33.0)† |
| HR (beats·min$^{-1}$) | 146.7 (21.7) | 151.6 (16.5) | 164.0 (14.6)† |
| $HR_{\%predicted}$ (%) | 88.9 (12.3) | 91.6 (9.2) | 99.0 (7.5)† |

Abbreviations: $\dot{V}O_{2peak}$, peak aerobic capacity(peak oxygen consumption); $\dot{V}CO_2$, peak carbon dioxide output; $RER_{peak}$, respiratory exchange rate; RR, respiratory rate; $\dot{V}E$, minute ventilation; $HR_{peak}$, peak heart rate; $HR_{\%predicted}$, the peak heart rate expressed as a percentage of the predicted peak heart rate.
* Significantly different from controls ($p < .05$).
† Significantly different from one-legged exercise (both tests are performed by controls; $p < .05$).
‡ In total three participants were taking β-blockers and therefore, were excluded in the calculation of $HR_{peak}$ and $HR_{\%predicted}$.

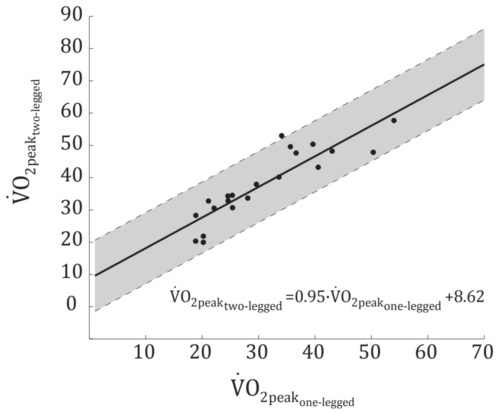


**Figure 3. Regression line.**

Regression line for the relationship between the peak aerobic capacity (peak oxygen consumption [$\dot{V}O_{2peak}$]) reached during the one-legged exercise test [$\dot{V}O_{2peak_{one-legged}}$]) and that reached during the two-legged exercise test ($\dot{V}O_{2peak_{two-legged}}$; n = 21). The high intra-class correlation coefficient (ICC(3,1) = 0.89 (95% confidence interval = 0.75 - 0.95; p < .001) revealed a strong relationship. The regression equation corresponding to the line is shown. The 95% error of estimate was calculated using 1.96± standard error of estimate and is shown in the Figure as a gray area.

reached similar levels of exertion. Nonetheless, the averaged value for peak aerobic capacity, peak carbon dioxide output, and minute ventilation were significantly lower for participants with an amputation than for controls (p = .02, p = .01, p = .04, respectively; Table 4). Figure 2 shows the oxygen uptake response and heart rate of a typical participant with a lower limb amputation during the exercise test.

Analyses of the one- and two-legged exercise tests, both performed by the controls, revealed that peak power output was 34.3% lower in the one-legged exercise test than in the two-legged exercise (p < .001). In the one-legged exercise test, the controls reached an average peak aerobic capacity of 30.8 $ml \cdot kg^{-1} \cdot min^{-1}$ (SD = 10.3); this value was significantly lower than that reached in the two-legged exercise test (37.9 $ml \cdot kg^{-1} \cdot min^{-1}$, SD = 11.0, p < .001; Table 4). The $HR_{peak}$ value was 7.5% lower during the one-legged exercise test; evidently this value also resulted in a lower $HR_{\%predicted}$ (91.6% versus 99%; Table 4). Despite the difference in the $HR_{peak}$ values, no difference in $RER_{peak}$ values was found between the one- and two-legged exercise tests. The $ICC_{(3,1)}$ for the one- and two-legged exercise tests was 0.89 (95% confidence interval = 0.75 - 0.95, p < .001; Figure 3). The standard error of the estimate calculated for the one-legged versus the two-legged exercise was 5.1 (Figure 3). The McNemar marginal homogeneity test revealed no statistical differences in limiting factors between the test modalities (p = .34; Table 2).

Multiple linear regression analyses revealed that the peak aerobic capacity measured using either the one-legged exercise test or the two-legged exercise test was associated with participants' age, BMI and sex. As expected, age and BMI were inversely associated with peak aerobic capacity, and men reached higher peak aerobic capacities than women. The percentage change, as calculated from

2

**Table 5. Regression Models.**

| Entered variables | β-coefficients | | | | $R^2_{adj}$ (p) |
|---|---|---|---|---|---|
| | β (95% CI) | $β_{stand}$ | p | %change | |
| **Model one-legged (n = 21)** | | | | | .703 (p < .001) |
| age | -0.017 (-0.032 - -0.003) | -.316 | p = .02 | -1.7% | |
| BMI | -0.052 (-0.075 - -0.029) | -.593 | p < .001 | -5.1% | |
| Sex (men[1]/women[2]) | -0.233 (-0.417 - -0.048) | -.347 | p = .02 | -20.7% | |
| **Model two-legged (n = 21)** | | | | | .607 (p < .001) |
| age | -0.020 (-0.037 - -0.004) | -.383 | p = .02 | -2.0% | |
| BMI | -0.040 (-0.066 - -0.014) | -.473 | p = .004 | -3.9% | |
| sex (men[1]/women[2]) | -0.226 (-0.430 - -0.022) | -.350 | p = .03 | -20.2% | |

The dependent variable was the natural log-transformed $\dot{V}O_{2peak}$.
Abbreviations: β, unstandardized beta coefficient; 95% CI, 95% confidence interval; $β_{stand}$, standardized beta coefficient; %change, the percentage change in peak aerobic capacity when the independent parameter is changed with one unit (e.g for the one-legged exercise a one year increase in age leads to a 1.7% reduction in peak aerobic capacity); $R^2_{adj}$, is the precision of estimate adjusted for the multiple explanatory variables in the model.

the regression analysis, revealed similar influences of age, BMI and sex on peak aerobic capacity in both the one-legged exercise and the two-legged exercise tests (Table 5).

## Discussion

The aims of the present study were to describe a discontinuous, graded, one-legged, peak exercise test and to determine whether it is a feasible and valid method for assessing the peak aerobic capacity in older people walking with a lower limb prosthesis.

### *Feasibility*

All participants were able to tolerate the exercise test, and none of the participants experienced post-exercise discomforts beyond short-term feelings of fatigue that were logically related to the exercise performed. The same proportions of participants that were able-bodied (controls) and participants who had an amputation indicated local fatigue to be the limiting factor during the exercise test, indicating that both groups experienced the same limitations. Even though upright cycling is a familiar activity for most people in The Netherlands, performing this activity with one-leg is not; hence, sufficient familiarization time is important. Although several participants needed guidance of the leg to improve cycling rhythm, none of the participants indicated this was a limiting factor during the exercise test. Whereas previous research has noted that when participants were asked to perform a more complex coordination pattern consisting of combined arm and leg activation, movement rhythm could become a limiting factor [197, 220].

Concerning the exercise protocol, the starting workload and the sizes of the incremental steps resulted in an overall (n = 57) average time to exhaustion that was well within the recommended maximum of 12 minutes [83, 146, 155] (Table 3). Nevertheless, for six participants (three controls and three with an amputation) the time to exhaustion exceeded the recommended 12 minutes by one and half minutes. Fortunately, the elongated exercise time did not lead to associated discomfort that might have limited exercise performance in these participants.

With regard to safety, numerous studies have indicated the importance of blood pressure and ECG monitoring in people with an amputation [3, 180, 197]. As was hypothesized, the rest intervals enabled accurate and regular blood pressure recordings and noise-free ECG tracings, thereby allowing adequate screening for cardiac abnormalities. To the contrary, adequate monitoring is limited during arm ergometry or combined arm and leg exercise because movements of the upper limbs produce low signal-to-noise ratio in ECG tracings [76, 171, 197, 220]. Because the exercise test in the present study was performed with the legs, the ECG also could be relatively accurately monitored during the exercise phase. These findings are in agreement with those of previous studies in which a discontinuous protocol was used to adequately monitor people with an amputation [12, 37, 70, 171]. During the rest phases the participants could indicate any discomforts, and the test leader was able to encourage the participants to try and complete the next exercise phase. We conclude that the discontinuous, graded, one-legged, peak exercise test is feasible because it proved to be both tolerable and safe in older people with a unilateral lower limb amputation.

*Validity*

To obtain a valid assessment of peak aerobic capacity, an exercise test should stress the cardiopulmonary system to a sufficient extent. However, a substantial amount of literature states that peak aerobic capacity is strongly dependent on the exercise mode and the muscle mass involved. Because of the limited active muscle mass involved during cycling with one-leg, the cardiopulmonary system might not be stressed to its full potential and exercise might be limited by peripheral factors [38, 145, 159, 191]. Additionally, because of vascular deficiencies or hemodynamic changes, people with an amputation might respond differently to a one-legged exercise test than people who are able-bodied [156]. Different criteria for determining whether the cardiovascular system has been stressed to its full potential have been used and discussed in the literature. In the present study we have chosen to use a $RER_{peak}$ value greater than 1.1 as the criterion for maximal effort. This choice was based on the grounds that the discontinuous nature of the protocol prevented a clear detection of a plateau in the oxygen uptake and because the considerable interindividual variability inherent in the age-corrected predicted maximal heart rate precludes the use of these parameters [113]. In total, 93.0% of the participants reached the *a priori* set criterion for maximal effort. These results, in addition to the fact that neither $RER_{peak}$ nor $HR_{peak}$ values differed between the groups, corroborated the notion that both older participants with an amputation and controls were able to stress the cardiopulmonary system to the same nearly maximal, extent during the one-legged exercise test.

Concurrent validity was determined by comparing the peak aerobic capacity reached in the one-legged test to that reached during the two-legged exercise test. In the one-legged exercise test, participants who were able-bodied (controls) were able to utilize 81.3% of the amount of oxygen utilized in the two-legged exercise test. This value is somewhat higher than the averaged value found for young participants [38, 123, 136, 145, 159-160]. Despite this systematic difference between both tests, the *a priori* set criterium (the lower bound of the confidence interval was ≤.75) for agreement between the tests was reached ($ICC_{(3,1)}$ 0.89, 95% confidence interval = 0.75 - 0.95) [135], indicating that the one-legged test is a good predictor for the peak aerobic capacity reached during the two-legged test. Nevertheless, there consisted a large interindividual variability in the relationship between the tests, as indicated by the rather high standard error of estimate. Interestingly, these rather high prediction errors corresponded to the magnitude of differences reported in other repeatability studies using a variety of exercise modes [197, 210]. These results indicated that the variation in agreement between one-, and two-legged exercise tests might depend on the test-retest variability and might be independent of the exercise mode used.

The associations between peak aerobic capacity and age, BMI and sex have been confirmed in numerous studies over the years. An analysis of construct validity revealed that the one-legged exercise test was able to replicate these associations. The nature of the relationship confirmed our expectation; age and BMI were negatively related, and men performed significantly better than women. A comparison of the established two-legged exercise test and the one-legged exercise test revealed that age, BMI and sex influenced the measured peak aerobic capacity to similar extents. For example, calculation of the percentage change (Table 5) revealed that when age was increased by one year, the peak aerobic capacity was predicted to be 1.7% lower when the equation based on the one-legged exercise test was used; this value is in agreement with the 2.0% reduction found using the regression equation based on the two-legged exercise test was used. These results demonstrated that the peak aerobic capacity measured with the one-legged exercise test was able to distinguish participants on the basis of age, BMI and sex to a similar extent, as would be expected when using a conventional peak exercise test.

The question remains as to whether the one-legged exercise test is a valid measure for assessing peak aerobic capacity and exercise tolerance. The aforementioned characteristics of the one-legged exercise test revealed that the controls and participants who had an amputation performed equally well with regards to maximal effort and that the one-legged exercise test had both a high concurrent and a high construct validity. Albeit, the one-legged exercise test did not stress the controls to the same extent as a two-legged exercise test given the systematic difference found between the tests in peak aerobic capacity and $HR_{peak}$. However, for people walking with a prosthesis, the capacity predicted by the two-legged exercise test is purely hypothetical and might not be valid because the additional muscle mass utilizing the oxygen in two-legged exercise is, in part, absent. As a consequence, the peak aerobic capacity measured with the one-legged exercise test could be regarded as a good approximation of the theoretical 'true' maximal aerobic capacity in people walking with a lower limb amputation. At least it targets the same muscles that are active during strenuous aerobic activities of daily living, thereby providing a good assessment of aerobic tolerance during daily activities.

*Limitation and future research*

Current research is subject to some limitations. The major limitation is that the participants with a lower limb amputation were all healthy and relatively active; all participants were able to ambulate with their prosthesis and had had their amputation for more than one year. As a consequence, the results cannot be generalized to people who have undergone amputation more recently and who are less active and possibly not accustomed to exercise. Therefore, future studies are needed to determine the applicability of the exercise test described here for this population. Future studies also should focus on the sensitivity and reproducibility of the exercise test and on providing insight into the magnitude of the difference that can be reliably detected at the individual level.

Furthermore, in the present study we tested the feasibility and validity of a one-leg cycle test. Perhaps other exercise modalities, such as those using the arms or a combination of the arms and legs, might provide an equally effective functional evaluation [12, 76]. However, arm ergometry might result in increased arterial pressure [76, 136, 191] and problems in obtaining reliable ECG tracings and blood pressure recordings [197], and exercise combining both the arms and legs might pose coordination difficulties which could hamper the feasibility of the exercise test. Because the present study focused merely on the applicability and validity of the discontinuous, one-legged, exercise test, we cannot conclude that the protocol is superior to other modalities. Further studies comparing different exercise modalities are needed.

**Conclusion**

The results of the present study demonstrated that the discontinuous, graded, one-legged, peak exercise test is feasible and provides a valid mean for assessing peak aerobic capacity and exercise tolerance in people walking with a lower limb prosthesis. The exercise test proposed in the present study can be easily implemented as the necessary equipment and adaptations are relatively inexpensive and widely available. The exercise set-up described here could be used as a safe and effective way to test people walking with a lower limb prosthesis. The test can help to assess the peak aerobic capacity and exercise tolerance and it can be used to design safe, effective, and individualized exercise programs. Further research to determine the ability of the protocol to detect changes in peak aerobic capacity and to determine the feasibility of the exercise test for other populations is warranted.